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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,372	10/26/2006	Minoru Kohara	KUZ0031US.NP	8112

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MARLTON, NJ 08053

EXAMINER
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SASTRI, SATYA B

ART UNIT	PAPER NUMBER
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1796

NOTIFICATION DATE	DELIVERY MODE
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01/12/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/584,372	<b>Applicant(s)</b> KOHARA, MINORU	
	<b>Examiner</b> SATYA B. SASTRI	<b>Art Unit</b> 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This office action is in response to amendment filed on 10/23/09. Claims 1-5, 8-13 are now pending in the application. The receipt of priority application, JP 2004-002491 is acknowledged.

#### ***Claim Objection***

2. Claim 12 is objected to because of the following informalities: The word “aluminate” is spelt incorrectly. Appropriate correction is required.

#### ***Previously Cited Statutes***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-5, 8-11, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasukochi et al. (WO 03/062342) in view of Hori et al. (US 6,146,656) and Tsubota et al. (US 5,049,417).

The discussions with regard to Yasukochi et al. and Hori et al. in paragraph 5 of the office action dated 7/28/09 are incorporated herein by reference.

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In summary, Yasukochi et al. disclose pressure sensitive adhesive and a patch comprising acrylic copolymers that include hydroxyethyl (meth)acrylate. Crosslinking agent such as boric acid or borates, in amounts ranging between 0.01 to 20 wt.% based on the adhesive composition are disclosed for crosslinking the hydroxyl groups under mild conditions. The compositions further include plasticizers such as silicone oil, naphthenic oil, plant oil etc. (col. 4, lines 30-34).

The prior art fails to disclose a patch (1) comprising the plasticizer and pseudo crosslinking compound within the presently recited range, (2) comprising a copolymer having hydroxyethyl (meth)acrylate within presently recited range, (3) comprising presently recited pseudo-crosslinking compound and (4) having presently recited properties.

Secondary reference to Hori et al. teach adhesive compositions comprising 25 to 200 parts by wt. of adhesive, of plasticizing liquids for imparting a soft feeling to the skin and also lowering the cohesive force during peeling (col. 5, lines 23-50). Thus, it would have been obvious to one of ordinary skill in the art to include plasticizers in any amount within the disclosed range in adhesive compositions of Yasukochi et al.

Additionally, with regard to the amount of hydroxyl group-containing monomer, Hori et al. disclose, the polymer includes as an essential ingredient, 1-50% by wt. and preferably, 3-20% by wt. of at least one monomer selected from carboxyl-containing monomer and a hydroxyl group-containing monomer, and if necessary, not greater than 40% by wt. of N- vinyl pyrrolidone (col. 4, lines 30-45). Furthermore, specific examples of disclosed polymers as well as working examples include a 2-ethylhexyl acrylate as a comonomer (col. 4, lines 47-56). Given the teaching that 1-50% by wt. of hydroxyl-containing monomer is advantageous from the viewpoint of adhesion properties such as adhesion and cohesion or releasability (col. 4, lines 30-

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22), it would have been obvious to one of ordinary skill in the art to include a hydroxy group-containing monomer from a small genus comprising two species, i.e. acid-containing monomer and hydroxyl-containing monomer, in any amount within the disclosed range of 1-50% by wt. of the copolymer, in the adhesive compositions of Yasukochi et al.

The Tusbota et al. reference discloses air-permeable adhesive tapes comprising acrylic type copolymers containing hydroxyl groups obtained from vinyl type monomers containing hydroxyl groups, such as 2-hydroxyethyl methacrylate (col. 4-5, bridging paragraph). Additionally, Tsubota et al. disclose that crosslinking agents suitable for adhesives having hydroxy groups include amino resin, epoxy compounds, boric acid, alkoxides of Ti, Zr etc. (col. 11, lines 22-33). It is noted that an amine compound as recited in instant claim 1 reads on the amino resin of Tsubota et al. Given the teaching by Tsubota et al. on equivalence and interchangeability of amino resin and boric acid as crosslinking agents for acrylic type copolymers containing hydroxyl groups, it would have been obvious to one of ordinary skill in the art to utilize any of the crosslinking agents, including amino resin in lieu of boric acid in the adhesive compositions of Yasukochi et al., based on their art recognized equivalence with a reasonable expectation of success. In the instant case, substitution of equivalent methods of crosslinking hydroxyl group-containing acrylic copolymer requires no express motivation, as long as the prior art recognizes equivalency. *In re Ruff* 118 USPQ 343 (CCPA 1958).

As noted in the office action dated 7/28/09, while the prior art is silent with regard to the limitations concerning shearing strain migration length recited in instant claim 1, it is the examiner's position that modified Yasukochi et al. adhesive composition must necessarily possess this property because the modified Yasukochi et al. meet the compositional requirements

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as recited in claim 1. As such, Yasukochi et al. disclose that hydroxy functional groups are less reactive compared to other functional groups, i.e. carboxy and amino groups and crosslinking of hydroxy group with borate may be accomplished under mild conditions (col. 1, lines 36-65). As noted above, borates, boric acid and amino resin are deemed functionally equivalent crosslinking agents based in Yasukochi and Tsubota et al. references. Additionally, given that an amine compound as recited in claim 1 reads on the disclosed amino resin (in Tsubota et al.), the amino resin must necessarily function as a pseudo- crosslinking compound. Thus, the presently recited properties in terms of shearing strain migration must necessarily be intrinsic to the modified Yasukochi et al. compositions, absent evidence to the contrary.

The discussion with regard to limitations in dependent claims 4, 5, 8-11 are adequately addressed in paragraph 5 of the office action dated 7/28/09 and is incorporated herein by reference. With regard to newly added claim 13, it is noted that working examples in Hori et al. disclose adhesive compositions comprising isopropyl myristate.

5. Claims 1-5, 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hori et al. (US 6,146,656) in view of Suzuki et al. (US 5,851,662).

Hori et al. disclose percutaneous absorption preparations in the form of a plaster, comprising acrylic copolymers and a plasticizer, in amounts of 25 to 200 parts by wt. of the pressure sensitive adhesive. With regard to the amount of hydroxyl group-containing monomer, Hori et al. disclose, the polymer includes as an essential ingredient, 1-50% by wt. and preferably, 3- 20% by wt. of at least one monomer selected from carboxyl-containing monomer and a hydroxyl group-containing monomer, and if necessary, not greater than 40% by wt. of N- vinyl

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pyrrolidone (col. 4, lines 30-45). Furthermore, specific examples of disclosed polymers as well as working examples include a 2-ethylhexyl acrylate as a comonomer (col. 4, lines 47-56).

Disclosed plasticizers in the working example include isopropyl myristate.

A plaster can be obtained by adhering a release paper on one side of the adhesive and a backing layer on the other side. In the skin contact base layer, a percutaneous absorption enhancer, stabilizing agent, drug dissolution aid or drug dissolution suppressing agent may be included (col. 6, lines 28-34).

The prior art fails to disclose a patch (1) comprising presently recited pseudo-crosslinking compound (2) comprising the plasticizer and pseudo crosslinking compound within the presently recited range and (3) having presently recited properties.

It is noted that the primary reference to Hori et al. is open to subjecting the adhesive to crosslinking treatment whereby skin irritation when the plaster is peeled and removed is reduced (col. 5, lines 33-37). Secondary reference to Suzuki et al. discloses adhesive sheets comprising a copolymer having carboxylic acid groups (ab.). Additionally, disclosed crosslinking agents for imparting removability include pyrocatechol usable in amounts of 1 to 10 parts by wt. of the copolymer (col. 9, lines 21-49). Given that the primary reference is open to the use of crosslinking agents and given the teaching by Suzuki et al. that pyrocatechol is suitable for imparting removability, it would have been obvious to one ordinary skill in the art to include the same in the adhesive compositions of Hori et al.

It is noted that phenol compound as presently recited in claim 1 reads on pyrocatechol. Furthermore, with regard to the ratio of plasticizer to crosslinking agent, it is noted that based on the working examples in Hori et al., the range overlaps in scope with presently recited range. In

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the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). See MPEP § 2144.05.

### ***Response to Arguments***

6. In view of the amendment, all previous rejections are withdrawn and new grounds of rejections are set forth above. Additionally, applicant's arguments with regard to the prior art of record have been fully considered but are deemed moot in view of the new rejections set forth above.

Presently amended claim 1 incorporates a Markush group for pseudo-crosslinking compound from previously presented claim 7 (now cancelled). However, the Markush group is amended to exclude boric acid, thus necessitating new grounds of rejection set forth above. In light of above, it is proper to make the present action final.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO



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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satya Sastri at (571) 272 1112. The examiner can be reached on Mondays, Thursdays and Fridays, 7AM-5.30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. David Wu can be reached on 571-272-1114.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satya B Sastri/

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